patient-centered treatment assessments and growth in risk sharing assessments will further increase the need for real-world PRO data.

PRM117

EXPLORING PATIENT PERCEPTIONS OF, AND PREFERENCES FOR, PAIN RESPONSE SCALES

Quadri N[1], Langel K[2], Muehlhausen W[1], O'Donohoe P[3], Wild D[1]
[1]Oxford Outcomes, An ICON plc Company, Oxford, UK, [2]CRF Health, Helsinki, Finland, [3]CRF Health, London, UK

OBJECTIVES: Scales measuring perceptions of pain can include numeric rating scales (NRS), visual analogue scales (VAS) and descriptor scales using words (adjectival). With the increased use of electronic data capture in clinical trial settings, such scales have been migrated to numerous platforms. After conducting a brief literature review, there was found to be a lack of research on the impact that migration of such pain scales can have on the efficacy of the scales. The objective of this study was to deploy three pain scales in different formats and on different platforms, and to explore preferences and perceived differences in patients who experience daily pain. **METHODS:** Twelve participants diagnosed with a range of conditions resulting in pain were interviewed in a qualitative interview setting. All participants completed three pain scales in different formats: NRS (11-, 9-, and 7-points; portrait/ landscape), VAS (horizontally/ vertically; portrait/ landscape) and adjectival scale (increasing/ decreasing severity). All scales were presented in three modes of administration: paper, handheld device and tablet device. Participants were asked about perceived differences and their preferences of the different scales, formats, and modes of administration. **RESULTS:** The NRS and adjectival scale were preferred equally (n=5). Participants expressed an almost unanimous preference for the 11-point NRS and increasing severity adjectival scale, across all administration modes. In contrast, the VAS was the least preferred scale (n=7) due to difficulty with interpretation. Participants expressed no usability problems with the tablet or handheld devices, but the tablet was preferred overall because of the bigger screen. **CONCLUSIONS:** Although the sample size makes generalising these findings difficult, this exploratory study suggests that the preferred pain scales may provide higher quality data as they are easier to interpret, and therefore minimise error and patient burden. Further evidence, particularly quantitative, is required to support these preliminary findings.

PRM118

METHODOLOGY FOR NEUROPSYCHOLOGICAL ASSESSMENT WORDLIST ADAPTATION

Simon M[1], Zarzar K[2], Settar C[3]
[1]TransPerfect, Paris, France, [2]TransPerfect, Research Triangle Park, NC, USA, [3]TransPerfect, New York, NY, USA

OBJECTIVES: Effective translation and adaptation of neuropsychological assessments is paramount to the successful collection of data in a global context. The structure and content of neuropsychological assessments requires specific processes for translation and adaptation to ensure appropriate understanding in each target language. Word list adaptation requires particular consideration, as various criteria must be met within and between wordlists – including but not limited to frequency, familiarity and cultural relevance to the target population, number of syllables, and avoidance of homonyms and repeated words. This review highlights important considerations for creation of target language word lists, and solutions for determining appropriate adaptation methodologies. **METHODS:** A review of previous translations of neuropsychological assessments, such as the ADAS, FCSRT, RBANS, MoCA, and MMSE, was performed. A review of translation procedures, developer involvement, guidelines for adaptation, translation methodology, linguistic decisions, and word list creation was conducted. **RESULTS:** Key solutions to ensure successful adaptation of wordlists include: 1) Outline all criteria used to develop the English word lists and assessment, 2) Create clear guidelines for adaptation of word lists in collaboration with the developer, if guidelines are not already available, 3) Employ a specialized project team of project managers, native-speaking medical linguists, and native-speaking neuropsychologists possessing extensive expertise in the relevant neuropsychological assessments. 4) Depending upon the assessment and the context of use, additional testing of the word lists with local populations to ensure comprehension may be warranted. **CONCLUSIONS:** Neuropsychological assessments and word lists require specialized translation and adaptation methodologies to ensure appropriate comprehension by the target population. Developer involvement in the creation of adaptation guidelines, and neuropsychologist involvement in the adaptation process are critical to ensuring adaptation is conducted appropriately. Further research is required to outline clear guidelines for situations requiring additional testing of the word lists with local populations to ensure comprehension.

PRM119

MAPPING BETWEEN COMPOSITE MEASURES IN PSORIATIC ARTHRITIS AND THE SF-6D: ANALYSIS FROM THE GRACE DATASET

Adams RC[1], Walsh C[2], Barry M[3], Fitzgerald O[4], Helliwell P[5]
[1]National Centre for Pharmacoeconomics, Dublin, Ireland, [2]Trinity College Dublin, Dublin, Ireland, [3]St. James's Hospital, Dublin, Ireland, Ireland, [4]St. Vincents University Hospital, Dublin Academic Healthcare, Dublin, Ireland, [5]University of Leeds, Leeds, UK

OBJECTIVES: Mapping or cross-walking is an accepted methodology for calculating utilities. Different models have been proposed for mapping from disease-specific quality-of-life (QOL) measures to generic QOL measures. Much of this work has been done using data from rheumatoid arthritis cohorts and using measures specific to RA. The objectives of this study are to test various statistical models to determine which provides the best fit for a psoriatic arthritis (PsA) cohort using both newly developed composite disease measures and established measures. The study also aimed to determine whether the composite disease measures provide a better estimate of utility over other measures and which components of the composite measures influence the relationship with QOL. **METHODS:** The data was made available from the Group for Research and Assessment of Psoriasis and Psoriatic Arthritis (GRAPPA) which collected data from an international cohort of PsA patients. Different regression models were used to estimate the relationship between the generic QOL measure, SF-6D and disease specific measures (HAQ,Composite Disease Activity Index (CPDAI), Psoriatic ArthritiS Disease Activity Score (PASDAS) and the Arithmetic Mean Desirability Function Score (AMDF). Model fit was determined using the R^2 statistic, root mean square error, Akaike information criterion; regression coefficients are also presented. **RESULTS:** The optimal model for each of the disease specific measures and SF-6D was a multiple regression model. The difference in model fit between the linear and multiple regression models was greatest for the composite disease measures specific to PsA. The CPDAI and AMDF provided the best fit to utility score followed by the PASDAS. **CONCLUSIONS:** PsA is a heterogeneous disease for which composite disease measures may be more appropriate than measures such as the HAQ. This study provides mapping coefficients, allowing utility estimation from these measures which may be collected in trials where no preference-based utility measure has been used.

PRM120

PATHWAYS TO EFFECTIVE CLINRO DOSSIER DEVELOPMENT

Bennett BM[1], Ballinger R[1], Nixon A[2]
[1]Oxford Outcomes, Oxford, UK, [2]Oxford Outcomes, Oxford , UK

OBJECTIVES: To highlight some of the common areas that require particular attention when preparing clinical outcome assessment (COA) dossiers, suitable for FDA regulatory label claims, with a particular focus on clinician-reported outcome (ClinRO) measures. The FDA has provided guidance for the use of Patient-Reported Outcome (PRO) measures for relevant endpoints in clinical trials to support label claims (FDA, 2009). Although several authors have indicated that the standards used to evaluate PRO's will apply to all COA's (Burke, 2011; Gwaltney, 2012), the FDA have not published guidelines on ClinRO measures to support label claims. This is surprising given that the ratio of label claims based on ClinRO's is approximately three ClinRO's to every PRO measure (Burke, 2010). **METHODS:** We conducted a review of the literature to ascertain the general level of use of ClinRO's and to find examples of widely used ClinRO's. The available evidence for these ClinRO's was then assessed by the standards of the PRO guidance, specifically in relation to content and construct validity, reliability and other psychometric properties. **RESULTS:** The literature review revealed that ClinRO's are common endpoints in clinical trials. However, it was also apparent from the sample of ClinRO's reviewed, that they fail to meet the evaluative standards prescribed by the FDA particularly in being "well defined and reliable". **CONCLUSIONS:** ClinRO's used as endpoints in clinical trials to support FDA label claims may lack the required evidence set out in the FDA PRO guidance document. Specifically, many ClinRO's have been developed by clinicians, and widely accepted by clinical peers, without undergoing psychometric evaluation. If the FDA were to evaluate ClinRO's to the same standards as PRO's, the ratio of label claims between ClinRO's and PROs may decrease significantly.

PRM121

BURDEN OF OSTEOARTHRITIS :DEVELOPMENT OF A QUESTIONNAIRE

Bertin P[1], Coudert T[2], Rannou F[3], Grange L[4], Taieb C[5]
[1]Comité LUtte contre la Douleur, Limoges, France, [2]PFSA, Boulogne Billancourt, France, [3]Hopital Cochin, Paris, France, [4]CHU Grenoble, Grenoble, France, [5]CREES PFSA, Boulogne, France

OBJECTIVES: Osteoarthritis (OA) also known as degenerative arthritis or degenerative joint disease, is a group of mechanical abnormalities involving degradation of joints. The daily-life of OA patient is considerably disturbed. The burden's concept assesses the individual burden, measuring the patient's disability generated by the disease in a broad sense.The aim of our study was to explore, using a questionnaire, how the burden of the OA affected a daily life, with the objective to better anticipate difficulties and thus provide better care **METHODS:** The development of the questionnaire we propose here was inspired by the construction of general QoL- questionnaires. Two steps are required for the development:, the creation in three stages following a strict methodological process involving a multidisciplinary team (doctors, social workers) and patients with OA who were interviewed; Secondly, the validation of the questionnaire by testing its reliability, its construct validity and its reproducibility. A cognitive debriefing was conducted to ensure its reproducibility. **RESULTS:** A population of 198 patients with OA was enrolled to answer to the questionnaire,(with SF12 and PGWI). We obtain a questionnaire called "Burden-Osteoartritis-New-Scale-BONeS". Exploratory assessments realized with a population showed that the concept of burden could be structured around 5 components: autonomy, daily life, family and personal relationships, work and psychological impact. 41 preliminary items were identified at the end of the verbatim. A final analysis managed to reduce to 28 items and a cognitive debriefing allowed to ensure its reproducibility. **CONCLUSIONS:** Chronic pathologies such as OA which remains a rare and incapacitating illness are difficult to assess by clinical or QoL aspects alone as their impact can be multidimensional. "BONeS" takes them all into consideration in order to explain every angle of the handicap generated. Our next objective is to develop the "BONeS" in German, Italian and Spanish with a cross cultural validation.

PRM122

ATOPIC DERMATITIS ON FAMILIES: CREATION OF A SPECIFIC BURDEN QUESTIONNAIRE

Meni C[1], Bodemer C[2], Toulon A[1], Branchoux S[3], Taieb C[4]